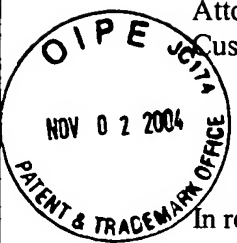


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Attorney Docket No.: 320727.00201  
Customer No. 27160

U.S. Patent Application No.  
10/620,433

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

John W. LUDLOW *et al.*

Application No.: 10/620,433

Filed: July 17, 2003

For: METHOD FOR OBTAINING VIABLE  
HUMAN CELLS, INCLUDING  
HEPATIC STEM/PROGENITOR CELLS

Group Art Unit: 1632

Examiner: Not Yet Assigned

Confirmation No.: Not Yet Assigned

Atty. Dkt. No.: 320727.00201

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

November 2, 2004

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. §1.56 and in accordance with the practice under 37 C.F.R. §§1.97 and 1.98, the Examiner's attention is directed to the documents listed on the enclosed Forms PTO/SB/08A and PTO/SB/08B. In accordance with current practice, copies of any listed U.S. Patent Documents are not being provided.

**FORMAL MATTERS**

In accordance with 37 C.F.R. § 1.97(b)(3), since a first Official Action on the merits of the subject application has not yet been issued, neither a certificate, petition nor payment of a fee is believed to be required for this Information Disclosure Statement. However, the Commissioner is hereby authorized to charge any fee which may be required in connection with this paper to Deposit Account No. 50-1710.

Attorney Docket No.: 320727.00201  
Customer No. 27160

U.S. Patent Application No.  
10/620,433

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned indicating that such information has been considered.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gilberto M. Villacorta", is written over a horizontal line.

Gilberto M. Villacorta, PH.D.

Registration No. 34,038

Sunit Talapatra, PH.D.

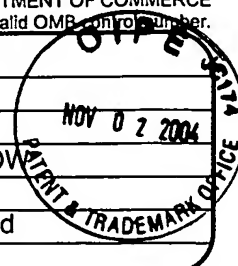
Registration No. 54,482

Patent Administrator  
KATTEN MUCHIN ZAVIS ROSENMAN  
525 West Monroe Street, Suite 1600  
Chicago, Illinois 60661-3963  
(202) 625-3500

**Complete if Known**

(Use as many sheets as necessary)

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|------------------------|------------------|
| Application Number     | 10/620,433       |
| Filing Date            | July 17, 2003    |
| First Named Inventor   | John W. LUDLOW   |
| Art Unit               | 1632             |
| Examiner Name          | Not Yet Assigned |
| Attorney Docket Number | 320727.00201     |



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| Sheet | 1 | of | 4 |
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| FOREIGN PATENT DOCUMENTS |                       |   |                                |   |   |                |
|--------------------------|-----------------------|---|--------------------------------|---|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T <sup>6</sup> |
|                          |                       | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                |   |   |                |
|                          | 5                     | WO 00/75275 A2  | 12/14/00                       | University of North Carolina                    |   | ✓              |
|                          |                       |   |                                |   |   |                |
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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| Attorney Docket Number | 320727.00201     |

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of

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**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
|                    | 6                     | Kubota H and Reid LM. 2000, "Clonogenic hepatoblasts, common precursors for hepatocytic and biliary lineages, are lacking classical major histocompatibility complex class I antigen", Proceedings of the National Academy of Sciences (USA) 97: 12132-12137.   | ✓              |
|                    | 7                     | Strom SC, Chowdhury JR, and Fox IJ. 1999, "Hepatocyte transplantation for the treatment of human disease (Review)", Seminars in Liver Disease 19: 39-48.  | ✓              |
|                    | 8                     | Fox et al., I. J., 1998, "Treatment of the Crigler-Najjar Syndrome Type I with hepatocyte transplantation," New England Journal of Medicine, 338:1422-1426.   | ✓              |
|                    | 9                     | Gupta et al., 1992, "Hepatocyte Transplantation: Development of New Systems for Liver Repopulation and Gene Therapy", Seminars in Liver Disease 12, 321.  | ✓              |
|                    | 10                    | Wilson et al., 1990, "Temporary Amelioration of Hyperlipidemia in Low Density Lipoprotein Receptor-Deficient Rabbits Transplanted with Genetically Modified Hepatocytes", Proceedings of the National Academy of Sciences USA 87:8437.                          | ✓              |
|                    | 11                    | Wu et al., 1991, "Receptor-Mediated Gene Delivery In Vivo", Journal of Biological Chemistry 266:14338.  | ✓              |
|                    | 12                    | Logan & Shenk, 1984, "Adenovirus Tripartite Leader Sequence Enhances Translation of mRNAs Late After Infection", Proc. Natl. Acad. Sci. USA 81:3655-3659.   | ✓              |
|                    | 13                    | Mackett et al., 1982, "Vaccinia Virus: A Selectable Eukaryotic Cloning and Expression Vector", Proc. Natl. Acad. Sci. USA 79:7415-7419.   | ✓              |
|                    | 14                    | Mackett et al., 1984, "General Method for Production and Selection of Infectious Vaccinia Virus Recombinants Expressing Foreign Genes", J. Virol. 49:857-864.   | ✓              |
|                    | 15                    | Panicali et al., 1982, "Construction of Poxviruses as Cloning Vectors: Insertion of the Thymidine Kinase Gene from Herpes Simplex Virus into the DNA of Infectious Vaccinia Virus", Proc. Natl. Acad. Sci. USA 79:4927-4931.                                    | ✓              |

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet 3 of 4

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|--------------------|-----------------------|---|----------------|
|                    | 16                    | Sarver, et al., 1981, "Bovine Papilloma Virus Deoxyribonucleic Acid: a Novel Eucaryotic Cloning Vector", Mol. Cell. Biol. 1:486.  | ✓              |
|                    | 17                    | Cone & Mulligan, 1984, "High-Efficiency Gene Transfer into Mammalian Cells: Generation of Helper-Free Recombinant Retrovirus with Broad Mammalian Host Range", Proc. Natl. Acad. Sci. USA 81:6349-6353.   | ✓              |
|                    | 18                    | Wigler, et al., 1977, "Transfer of Purified Herpes Virus Thymidine Kinase Gene to Cultured Mouse Cells", Cell 11:223.   | ✓              |
|                    | 19                    | Szybalska & Szybalski, 1962, "Genetics of Human Cell Lines, IV. DNA-Mediated Heritable Transformation of a Biochemical Trait", Proc. Natl. Acad. Sci. USA 48:2026.  | ✓              |
|                    | 20                    | Lowy, et al., 1980, "Isolation of Transforming DNA: Cloning the Hamster apt Gene", Cell 22:817.   | ✓              |
|                    | 21                    | Wigler, et al., 1980, "Transformation of Mammalian Cells with an Amplifiable Dominant-Acting Gene", Proc. Natl. Acad. Sci. USA 77:3567.   | ✓              |
|                    | 22                    | O'Hare, et al., 1981, "Transformation of Mouse Fibroblasts to Methotrexate Resistance by a Recombinant Plasmid Expressing a Prokaryotic Dihydrofolate Reductase", Proc. Natl. Acad. Sci. USA 78:1527.   | ✓              |
|                    | 23                    | Mulligan & Berg, 1981, "Selection for Animal Cells that Express the Escherichia coli Gene Coding for Xanthine-guanine Phosphoribosyltransferase", Proc. Natl. Acad. Sci. USA 78:2072.   | ✓              |
|                    | 24                    | Colberre-Garapin, et al., 1981, "A New Dominant Hybrid Selective Marker for Higher Eukaryotic Cells", J. Mol. Biol. 150:1.  | ✓              |
|                    | 25                    | Santerre, et al., 1984, "Expression of Prokaryotic Genes for Hygromycin B and G418 Resistance as Dominant-Selection Markers in Mouse L Cells", Gene 30:147.   | ✓              |

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|  |   |    |   | Examiner Name            | Not Yet Assigned |
| Sheet  | 4 | of | 4 | Attorney Docket Number   | 320727.00201     |

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|                                 | 26                    | Hartman & Mulligan, 1988, "Two Dominant-acting Selectable Markers for Gene Transfer Studies in Mammalian Cells", Proc. Natl. Acad. Sci. USA 85:8047.  | ✓              |
|                                 | 27                    | Naldini et al., 1996, "In Vivo Gene Delivery and Stable Transduction of Nondividing Cells by a Lentiviral Vector", Science 272:263-267.   | ✓              |
|                                 | 28                    | Brister et al., 2002, "Hepatitis C Virus Non-Structural Protein 3-Specific Cellular Immune Responses Following Single or Combined Immunization with DNA or Recombinant Semliki Forest Virus Particles", J. Gen. Virol. 83 (Pt. 2):369-381.                      | ✓              |
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